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09/295,691	04/21/1999	JON FAIZ KAYYEM	A-67465/RFT/	7483

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EXAMINER

STARSIK, JOHN S

ART UNIT

PAPER NUMBER

1743

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14

Please find below and/or attached an Office communication concerning this application or proceeding.

MF=14

Office Action Summary

Application No. 09/295,691	Applicant(s) Jon Fair Kayem	
Examiner J. STARSIAK	Group Art Unit 1743	

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address —

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- ☒ Responsive to communication(s) filed on 21 MARCH 2002
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 36-53 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

- ☒ The proposed drawing correction, filed on 19 June 2002 is ☐ approved ☒ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some* ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))
- *Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Stat ment(s), PTO-1449, Paper No(s). _____
- ☒ Notice of R ference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Pat nt Drawing Review, PTO-948
- ☐ Int rview Summary, PTO-413
- ☐ N tice of Informal Pat nt Application, PTO-152
- ☐ Other _____

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DETAILED ACTION***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “detection electrode”, the “self-assembled monolayer”, and the “binding ligand” recited in claim 36; the “filter” recited in claim 39; the ~~“cell capture structure provided in said sample handling well” recited in claim 40~~; the ~~“cell separation structure provided in said sample handling well” recited in claim 42~~; the electrophoretic ~~microchannel and electrodes~~ recited in claim 43, all the structure recited in claim 45 recited in claim 45, “the electrical resistance heater positioned in said reaction module” recited in claim 47; ~~the resistance heater positioned in said sample handling module” recited in claim 48~~, the “means for inducing flow” recited in claim 49; the “pump” recited in claim 50, the ~~“means for holding said sample” recited in claim 51~~; and the “valve” recited in claim 52 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-44 and 48 Claim rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. .

The above claims do not have support in the application as originally filed. Specifically, claim 41 recites, "a cell capture structure *provided in said sample handling well*". Claim 42 recites, "a cell separation structure *provided in said sample handling well*". Although the term "sample handling well" is used in the brief description of the drawings (only place in the specification this term is used), the portion of the specification which corresponds to these claims, i.e., page 11, line 26-page 15, line 23, is devoid of the use of the term . In other words none of the structure in these claims is described as being in a "sample handling well" in the specification.

~~Claim 48 recites, "an electrical resistance heater positioned in said sample handling well". While page 38, lines 16-24 support electrical resistance heaters for the reaction chamber (claim 47) they do not support claim 48.~~

Claims 36-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Despite the length of the specification (113 pages) the portion of the specification directed to the structure of the device (a device is being claimed). Instead the bulk of the specification is directed to long lists of possible options for the "self-assembled monolayer" and "ligands". Also [✓]there is a long lists of possible processes performed in the sample handling module and the reaction module. Moreover, the only portion of the specification directed the the structural organization of the possible elements of the invention is the brief description of the drawings. The remainder of the specification is directed to specific examples for each of the elements, individually. Moreover, some elements are not even described. For example, it is obvious that the "detector electrode" requires a counter- electrode. Yet, the specification is devoid of of any discussion of a counter electrode. Similarly in order to inject fluid containing the sample into the device fluid from somewhere in the device must exit. The specification provides no structure for this.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36-53 are rejected as incomplete. Specifically, the combination of elements recited as "a detection module" cannot perform the detection function. From pages 98-110 of the

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specification it appears that all embodiments of the detector module require elements in addition to those recited in claim 36. The additional elements depend of the technique used. For example if fluorescence detection is used a light source and a photodetector are required. Also, a counter electrode is required. Claim 51 recites "a means for holding said sample". It is unclear what limitation is intended by this recitation, particularly in view of the recitation in claim 52 that "said means for holding said sample is a valve". The function recited in claim 51 does not correspond to the function of a valve.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claims 36 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Segal et al..

Segal et al. teaches [col. 8, lines 47-53]: “In one embodiment, the diagnostic card device of the present invention includes the following elements which will be further described herein below: a support substrate, which includes a sample introduction region, a biosensor, a sample flow pathway communication with said sample-introduction region and said biosensor...”. See Figures 8A and 16. Segal et al. teaches [col. 11, lines 36-53]: “The devices can include, in conjunction with the sample-introduction region, means for sample pre-treatment, such as filters for red blood cells....The device can include a separation device for filtering the sample....Sample pretreatment can also reduce or remove interfering substances such as immunochemical cross-reactants, redox substances and the like.”. The detector elements recited on several embodiments of the biosensors of Segal et al., particularly the embodiment illustrated in figure 13 and described from col. 15, line 18 to col. 16, line 38.

Response to Arguments

Applicant's arguments filed 21 March 2002 have been fully considered but they are not persuasive.

Applicant's arguments that the examiner's rejection of the claims under 35 USC 112 and his objection to the drawings should be withdrawn in view of the fact that there is a new set of claims in the application is moot in view of the new grounds of rejection/objection.

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Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Starsiak Jr. whose telephone number is (703) 308-1797. The examiner can normally be reached on Monday to Wednesday from 8:00 AM to 3:30 PM and on Thursday and Friday from 8:00 AM to 12:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


John S. Starsiak Jr.

23 May 2002


Jill Warden
Supervisory Patent Examiner
Technology Center 1700